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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,983	04/08/2004	Lawrence Steinman	690068.412C4	9886
500	7590	12/06/2004	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC			RUSSEL, JEFFREY E	
701 FIFTH AVE			ART UNIT	
SUITE 6300			PAPER NUMBER	
SEATTLE, WA 98104-7092			1654	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/820,983

**Applicant(s)**

STEINMAN ET AL.

**Examiner**

Jeffrey E. Russel

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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1. The disclosure is objected to because of the following informalities: At page 1, line 5, the status of parent application 10/270,707 should be updated. At page 1, line 9, the filing date of the patent application should be inserted. At page 6, line 25, the SEQ ID NO should be inserted. At page 18, line 28, "rates" should be changed to "rats". Appropriate correction is required.

The amendments to the specification filed November 5, 2004 have not been entered because they are not in proper format under 37 CFR 1.121(b). The amendments to pages 6 and 18 of the specification were not in the form of replacement paragraphs, as required by 37 CFR 1.121(b)(1)(ii). The amendment to page 23, line 2 of the amendment, changes the word "doses" to "does" without marking as required by 37 CFR 1.121(b)(1)(ii).

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 6-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to peptides, compositions comprising the peptides, and methods of using the peptides, in which the peptides comprise residues 87-99 of hMBP in which at least the lysine residue at position 91 is altered to another amino acid. The claims recite peptides having any sequence, as long as one amino acid is present which is not L-lysine, because the "at least" language at claim 6, line 3, and claim 7, line 4, permits alteration of other amino acids in addition to the one at a position corresponding to position 91 of hMBP. Of the

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peptides which are recited in the claims, which are unlimited with respect to length and are essentially unlimited with respect to sequence, Applicants disclose ten examples (see, e.g., Figure 3), each of which has the same length and the same sequence except for the amino acid at the position corresponding to position 91 of hMBP. Applicants do not describe any structural features necessary for the peptide analogues to bind to MHC or for the peptide analogues to be useful for treating multiple sclerosis. In view of the large genus of peptides recited in the claims, the limited number of specific peptides described in the specification, and the lack of any described correlation between the structure of the peptides and their function in binding to MHC and treating multiple sclerosis, one skilled in the art would not recognize that Applicants had within their possession the entire claimed genus of peptides, and the claims thus lack an adequate written description.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,740,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '638 patent anticipate the instant claims.

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6. Claims 6-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,489,299. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-4 of the '299 patent anticipate instant claim 6. With respect to instant claims 7-11, it would have been obvious to one of ordinary skill in the art to use the composition claimed in the '299 patent in accordance with its claimed intended use.

7. Claims 6-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,369,033. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '033 patent anticipate the instant claims. Note that a method of using a compound, including the alanine analogue of claim 7 of the '033 patent, anticipates claims drawn to a method.

8. Applicant's arguments filed November 5, 2004 have been fully considered but they are not persuasive.

The rejection under 35 U.S.C. 112, first paragraph is maintained. The ten peptides exemplified in the specification, which are of identical length and identical sequence except for one amino acid, are not representative of the claimed genus of peptides, which can be of any length which is at least 13 amino acids and which can be of any sequence as long as at least one residue is not lysine. The in vitro, in vivo, and clinical trial data involving the ten particular peptides does not show that Applicants had within their possession the entire claimed genus of peptides. Note that the examiner in no way questions the enablement or written description of the ten particular peptides.

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The anticipation rejection over the Martin et al article is withdrawn for the reasons set forth in Applicants' response, page 9, lines 8-15.

The obviousness-type double patenting rejections are maintained because the corrected terminal disclaimers referred to by Applicants in the remarks were not found attached to the response. Note also that in the Transmittal Form, the box for Terminal Disclaimer is unchecked.

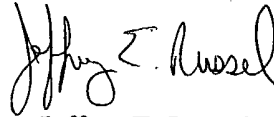
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large initial "J" and a prominent "E".

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

November 30, 2004